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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,301	09/18/2006	Shuo Shen	5463-2PUS	4813

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EXAMINER	
MOSHER, MARY	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
11/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,301	SHEN ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) *1-7,12,14-16,19,21-36,42,44,45 and 47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-11,13,17,18,20,37-41,43,46 and 48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of group III, claims 8-11, 13, 17, 18, 20, 37-41, 43, 46, 48 in the reply filed on 9/17/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-7, 12, 14-16, 19, 21-36, 42, 44, 45, 47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/17/2007.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 8-11, 18, 37-41 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The antibodies, as claimed, have the same characteristics and utility as those found naturally in SARS-infected patients, and therefore do not constitute patentable subject matter. See American Wood v. Fiber Disintegrating Co., 90 U.S. 566 (1974); American Fruit Growers v. Brogdex Co., 283 U.S.1 (1931); Funk Brothers Seed Co. v. Kalo Innoculant Co., 33 U.S. 127 (1948); Diamond v. Chakrabarty, 206 USPQ 193 (1980). This rejection could be obviated by amending the claims to recite "isolated" or "purified" antibodies.

Claim Rejections - 35 USC § 112

Claims 8-11, 13, 17, 37, 38, 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is drawn to an antibody to a fragment of SEQ ID NO:1 which comprises SEQ ID NO:5. It is not clear what is meant by this claim. Since an antibody binds to a single epitope, which is typically less than 10 amino acids long (for a linear epitope), it is not clear if the claimed antibody is limited to ones which bind to epitopes found in SEQ ID NO:5, or if it is open to antibodies that bind any epitopes found in SEQ ID NO:1. If the broader scope is intended, then the limitation of "said fragment comprising SEQ ID NO:5" is meaningless. If the narrower scope is intended, then claims 9-11 fail to further limit claim 8. This problem affects dependent claims 13, 17.

Claim 37 is drawn to a mature, glycosylated spike protein "or a part thereof". Is the intent to open the scope of the claim to antibodies which bind any part, including nonglycosylated parts? This renders the intended scope of the claim unclear. In claim 38, it is not clear what an "anti-transmembrane domain" is, the term is not defined in the specification. Therefore, the characteristics of antibodies which bind to this protein are not clear. This affects dependent claim 48.

Claims 17, 46, 48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

invention. These claims are drawn to a vaccine to treat or prevent the onset of SARS, comprising an anti-S antibody. The specification teaches that some antibodies neutralize virus infectivity in cultured cells. However, there is no working example showing successful treatment or prevention of disease. The prior art contains conflicting evidence on the efficacy of neutralizing antibodies to treat or prevent other coronavirus diseases, and contemporary uncertainty on which of the coronaviruses (if any) provide a reasonably model for SARS. See for example the reviews by Saif (Veterinary Microbiology 37:285-297, 1993) and Cavanaugh (Avian Pathology 32:567-582, 2003). Therefore, one skilled in the art would not unquestioningly accept assertions regarding the efficacy of an untested antibody in prevention or therapy. Furthermore, considering the extraordinary virulence of SARS infection, those skilled in the art would require extensive guidance in effective means of administration of preventive or therapeutic antibodies. Considering the limited teachings in the specification, the unpredictability of the art, the absence of working examples, and the state of the art, it is concluded that undue experimentation would be required to enable the claimed vaccines.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 8-11, 18, 37-41 are rejected under 35 U.S.C. 102(a) as being anticipated by Li et al (Genomics, Proteomics, and Bioinformatics 1:108-117, May 2003).

In applicant's lexicography, SEQ ID NO:5 corresponds to S protein residues 1055-1192, the HR2 heptad region is somewhere within 1029-1192, S1 fragment corresponds to 48-358, S3 corresponds to 168-461, S2 corresponds to 362-790, S9 corresponds to 798-1055. Li et al teaches SARS patient antibodies which bind to residues 1130—1147 (within SEQ ID NO:5 and the HR2 heptad region), 301-322 (within both S1 and S3 fragments), 599-620 (within fragment S2), see Table 2. Therefore, the reference antibodies clearly meet the limitations of claims 8-11 and 18. In addition, since the synthetic peptides of Li constitute parts of a mature, glycosylated spike protein, the antibodies binding to the Li peptides would also bind to mature, glycosylates spike protein. Therefore, the reference antibodies also meet the limitations of claims 37-41.

Claims 8-11, 13, 17, 18, 20, 37-41, 43, 46, 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Dimitrov et al WO 2005/001034. Dimitrov teaches numerous fragments of the SARS S protein, see for example pages 52-54, 56-70 and SEQ IDs 13-15, 20-55. Dimitrov also teaches antibodies which bind to the fragments, body-treating compositions which comprise the antibodies, and kits containing the antibodies, see for example claims 49-65, 75-77, 81. This disclosure is supported as far back as 21 July 2003 in application 60/489166. Therefore the reference meets each and every limitation of these claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13, 20, 43 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Li et al (Genomics, Proteomics, and Bioinformatics 1:108-117, May 2003). Claims 13, 20, and 43 are drawn to kits comprising the antibody of claims 8, 18, and 37, respectively, and do not require any other components. As discussed above, Li discloses antibodies meeting the limitations of claims 8, 18, and 37. The antibodies of Li are deemed to anticipate the kit compositions as claimed since the claims require nothing beyond the antibodies themselves. Although Li does not disclose "kits" *per se*, the compositions of Li are deemed to be the same as the claimed kits since the components are the same; if not,

packaging reagents to be used together in the form of kits is conventional and done for reasons of convenience and economy and would have been obvious over Li.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on varying dates and times; please leave a message..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mary E Mosher, Ph.D.
Primary Examiner
Art Unit 1648

11/28/07